

Thursday, 29 May 2025

# **Hiccup For Heart Tech**

Evolution Capital provides an update on Echo IQ ('EIQ'), downgrading our recommendation from 'Spec Buy' to 'Hold' and revising our price target to \$0.30 (see Valuation section of this update report for full explanation). On Tuesday, 20<sup>th</sup> of May 2025, EIQ announced an update on their application to the American Medical Association ('AMA') for a dedicated category III CPT code for EchoSolv-AS in the US. The Company advised that this application was unsuccessful.

## What Is All the Fuss About?

EIQ's business model is centred around a "utilisation-indexed SaaS licence". This is a hybrid contract structure that borrows the pricing basis from per-test deals commonly seen between US hospitals and device/diagnostic vendors, but packages it as a fixed-fee software subscription. EIQ's annual subscription fee is equal to the no. of Echocardiograms performed p.a. multiplied by the reimbursement rate associated with the CPT code multiplied by the estimated average approval rate of reimbursement claims associated with the CPT code. Currently, EchoSolv-AS is covered by Miscellaneous CPT code 93799, which is reimbursed at US\$100-150, 20-40% of the time. In practice, a hospital conducting 4,000 echocardiograms per annum would be charged 4,000 \* US\$100 (baseline) \* 30% (midpoint), totalling US\$120,000 per annum.

Importantly, a category III CPT code is likely to have been reimbursed at a higher rate and more often, 40-60% of the time. Our modelling assumed baseline reimbursement in this scenario at US\$150. Using our previous example, a hospital conducting 4,000 echocardiograms per annum would be charged US\$300,000 per annum with a category III CPT code. Until this milestone is achieved, there is an estimated opportunity cost of 150% of current revenue generation capacity.

## Is It All Doom and Gloom?

Short answer, no. EIQ is actively progressing revisions to its submission for the next CPT Editorial Panel Cycle and will resubmit prior to the deadline of 11 June 2025. The Company will then present its application in September 2025, and, should this be successful, a dedicated category III CPT code will be issued shortly thereafter.

If EIQ misses again, there are options. Code 93799 can be billed indefinitely, meaning there is no sunset date on EchoSolv-AS reimbursement in the current format. Looking elsewhere, EIQ could file for NTAP (New Technology Add-on Payment), a Medicare program that provides reimbursement to hospitals for new and innovative medical services and technologies. CMS has shown it will pay AI echo tools via NTAP or assign them to a New-Tech APC even without a proprietary CPT code. An example is NTAP code XXE2X19, used by Ultromics for their EchoGo HF product in hospital inpatient settings. As outlined in our initiation report, EchoGo HF is an FDA-cleared cloud-based AI solution that analyses echocardiogram clips to flag heart failure with preserved ejection fraction. XXE2X19 is eligible for up to \$1,023.75 per acute hospital stay.

**The bottom line** is that EIQ still has several levers: improve its category III dossier for the September cycle, pursue NTAP or APC, all while simply continuing to claim 93799.

# ASX:EIQ Healthcare Update Report

| Recommendation | Hold   |
|----------------|--------|
| Previous Close | \$0.25 |
| Target Price   | \$0.30 |

### Company Profile

| Market Cap      | ~A\$161.3M      |
|-----------------|-----------------|
| SOI (undiluted) | ~645.2M         |
| Free Float      | ~75.3%          |
| ADV (3-month)   | ~A\$1.38M       |
| 52-Week Range   | \$0.13 - \$0.37 |

### **Price Performance**



### **Company Overview**

Echo IQ Limited (ASX: EIQ) is an medical Australian technology specialising in Al-driven company solutions to improve clinical decision making in cardiology. The company's flagship product. EchoSolv. leverages advanced AI and proprietary algorithms to enhance the diagnosis and assessment of severe structural heart diseases, particularly Aortic Stenosis (AS) and Heart Failure (HF). Validated through rigorous clinical studies, EchoSolv-AS received FDA 510(k) clearance in October 2024 and is now in commercialisation through integration partnerships with leading imaging software providers and large hospital networks across the US.

### Analyst

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|--------------------|-------------|
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Click <u>here</u> to access Evolution Capital's Initiation Report of EIQ published 23 April, 2025.

# **Category III CPT Codes**

Let's get to the crux of the matter. Category III codes give temporary tracking identifiers for new, emerging or experimental technologies, services, or procedures that do not yet satisfy the evidence and utilisation test needed for permanent category I codes. They let clinicians bill uniformly, and let payers and researchers collect real-world utilisation and outcome data while evidence is still maturing. Applications are reviewed by the AMA CPT Editorial Panel, who meet three times a year. The submission dossier must include a full procedure description and at least one peer-reviewed article but does not need widespread utilisation.

Every Cat III code is automatically slated for panel review five years after its effective date. If, by then, the underlying service has (i) adequate peer-reviewed evidence of safety and clinical efficacy, and (ii) sufficient national utilization, the sponsor – in this case, EIQ, can request promotion to Cat I. The 5-year clock prevents the CPT manual from filling up with little-used or never-validated procedures. It forces sponsors either to finish the evidence work or concede that uptake is too low to justify a permanent code. Moreover, because payers know Category III codes are provisional, they can (and often do) require prior authorisation or refuse payment until stronger data emerge. That pressure helps align reimbursement decisions with clinical value.

These Cat III codes are deliberately temporary: they serve as a data-collection bridge between commercialisation and mainstream clinical adoption. The five-year sunset ensures that only technologies that prove their worth, achieve real-world uptake, and reach consensus support are rewarded with a permanent Cat I code, while those that fail to deliver quietly disappear.

What has us a little bit worried? Echo IQ has made it to the start line but missed the gun. Rejection by the AMA delays broad reimbursement clarity, introduces financial uncertainty for potential hospital customers, and risks slower adoption, highlighting why securing a Category III code is crucial for achieving substantial and timely commercial success.

# Valuation

Considering last week's announcement, we must update our DCF model assumptions with the available information. Our initiation report assumed EIQ attained category III by the end of FY25 and that category III is reimbursed at US\$150 on average 50% on the time. To reflect the risk of rejection in the September cycle, we have constructed four distinct scenarios as outlined in figure 1.

In our initial assumptions, we anticipated favourable yet highly realistic adoption of EchoSolv-AS. Without Cat III, we assume hospitals are less incentivised to bring-on the technology. Reimbursement uncertainty is the single biggest adoption brake. Approximately 30% of claims are reimbursed under 93799, which has no preset fee – every claim is manually reviewed. Value analysis committees see real cash-out risk resulting in hospitals typically waiting for a guaranteed payor pathway.

Moreover, historical analogues corroborate the slower adoption curve. For instance, HeartFlow's FFRCT technology experienced limited adoption initially, achieving fewer than 40 hospital installations across the NHS by 2018-2019. However, following the establishment of a dedicated Category III CPT code in January 2018 and supportive CMS reimbursement via a New Technology APC, HeartFlow's adoption accelerated sharply, reaching over 725 hospitals globally by 2022. Similarly, IDx-DR, an autonomous AI diagnostic tool for diabetic retinopathy, saw minimal Medicare claims before its dedicated CPT code (92229) took effect in 2021. Following this, Medicare claims for IDx-DR surged, surpassing 15,000 within two years. These cases illustrate that the presence of a dedicated reimbursement pathway significantly accelerates market adoption, validating a more conservative forecast for EchoSolv-AS given its current reliance on the miscellaneous CPT code 93799.

As outlined in our initiation of coverage, the valuation story of EIQ relies on the Company's ability to scale across the US. Here we have a hiccup. A hiccup and hopefully not much more. Through DCF methodology, we calculate fair valuation under four scenarios:

Figure 1: DCF valuation scenarios for EchoSolv-AS under four reimbursement and adoption pathways, illustrating how the absence or timing of Category III and Category I CPT codes affects reimbursement structure, hospital uptake by FY30, and resulting equity value and fair price.

|                            | Scenario A   | Scenario B   | Scenario C   | Scenario D   |
|----------------------------|--|--|--|--|
| Case                       | Downside   | Conservative   | Base   | Upside   |
| Reimbursement              | No Cat III CPT Code.   | Cat III CPT Code<br>received in time for<br>reimbursement at start<br>FY27. No Cat I code in<br>forecasted period.   | Cat III CPT Code<br>approved in September<br>review Cycle, ready for<br>use in H2 FY26. No Cat I<br>code in forecasted<br>period.                              | Same as Scenario C but<br>with a Cat I approved in<br>time for start of H2<br>FY29.                              |
| Reimbursement<br>Structure | Misc: avg. US\$100 rate;<br>30% claim success.   | Misc: same as Scenario<br>A.<br>Cat III: avg. US\$150 rate;<br>50% claim success.  | Same as Scenario A.  | Misc & Cat III: same as<br>Scenario A.<br>Cat I: avg. US\$200 rate;<br>80% claim success.                        |
| Adoption                   | Very slow adoption.<br>Approximately 150<br>hospitals by end FY30<br>each performing on<br>avg. 4,000 applicable<br>echos per annum. | Slow adoption prior to<br>Cat III, followed by<br>'normal' adoption rate.<br>Approximately 220<br>hospitals by end FY30<br>each performing on<br>avg. 4,000 applicable<br>echos per annum. | Accelerated adoption<br>upon Cat III receipt.<br>Approximately 280<br>hospitals by end FY30<br>each performing on<br>avg. 4,000 applicable<br>echos per annum. | Same as Scenario C,<br>however, upon Cat I<br>reimbursement receipt,<br>rapid scaling of<br>operations. Hospital |
| DCF Assumptions 8          | Outputs  |  |  |  |
| WACC                       | 14.5%  | 14.5%  | 14.5%  | 14.5%  |
| Terminal Growth Rate       | 2.5%   | 2.5%   | 2.5%   | 2.5%   |
| Equity Value               | A\$50.5M   | A\$155.3M  | A\$204.4M  | A\$445.2M  |
| Fair Valuation             | A\$0.07  | A\$0.24  | A\$0.31  | A\$0.69  |

### We downgrade our Target Price to A\$0.30 and our recommendation to Hold.

Our Target Price is based on the base case scenario, being Scenario C, adjusted down to reflect the risk of rejection in the September cycle and the consequential impact on revenue.

Across all scenarios, no further capital is required to be raised. We also assume no option conversion, no performance rights exercised nor issued, no further investment in PPE, and no M&A activity. To limit speculation, we do not factor-in revenues from EchoSolv-PH. The WACC has increased from 12.4%, used in the modelling for the initiation report, due to an increase in Beta (0.78 to 1.11). Our margin assumptions remain unchanged from the initiation report.

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# **Financial Statements**

Statement of Cashflows

| Income Statement            |        |        |        |        |        |
|-----------------------------|--------|--------|--------|--------|--------|
| A\$'000s                    | FY24a  | FY25e  | FY26e  | FY27e  | FY28e  |
| Revenue                     | 0.04   | 0.43   | 5.23   | 44.84  | 65.27  |
| Other Income                | 2.00   | 2.13   | 1.07   | -      | -      |
| Total Revenue               | 2.04   | 2.56   | 6.30   | 44.84  | 65.27  |
| Operating expenses          | -6.85  | -7.30  | -3.66  | -30.27 | -42.43 |
| EBITDA                      | -4.81  | -4.74  | 2.64   | 14.57  | 22.85  |
| D&A                         | -0.60  | -0.59  | -0.58  | -0.40  | -0.40  |
| EBIT                        | -5.41  | -5.33  | 2.06   | 14.18  | 22.45  |
| Net Interest                | -      | -      | -      | -      | -      |
| NPBT                        | -5.41  | -5.33  | 2.06   | 14.18  | 22.45  |
| Tax expense                 | -      | -      | -0.62  | -4.25  | -6.73  |
| Discontinued operations     | -      | -      | -      | -      | -      |
| NPAT                        | -5.41  | -5.33  | 1.44   | 9.92   | 15.71  |
|                             |        |        |        |        |        |
| Balance Sheet               |        |        |        |        |        |
| A\$'000s                    | FY24a  | FY25e  | FY26e  | FY27e  | FY28e  |
| Cash                        | 2.12   | 20.75  | 23.76  | 33.48  | 50.20  |
| Receivables                 | 0.10   | 0.17   | 1.31   | 8.52   | 11.75  |
| Other                       | 0.24   | 0.70   | 0.56   | 0.32   | 0.26   |
| Current assets              | 2.45   | 21.62  | 25.63  | 42.32  | 62.20  |
| Receivables                 | -      | -      | -      | -      | -      |
| PPE                         | 0.01   | -      | -      | -      | -      |
| Intangible assets and Other | 5.79   | 7.21   | 4.63   | 5.43   | 4.34   |
| Non-current assets          | 5.80   | 7.21   | 4.63   | 5.43   | 4.34   |
| Total assets                | 8.26   | 28.82  | 30.26  | 47.75  | 66.54  |
|                             |        |        |        |        |        |
| Trade and other payables    | 1.36   | 1.10   | 0.88   | 8.58   | 11.23  |
| Borrowings                  | 0.13   | -      | -      | -      | -      |
| Other                       | 0.13   | -      | 0.22   | 0.09   | -      |
| Current liabilities         | 1.49   | 1.10   | 1.09   | 8.66   | 11.23  |
| Borrowings                  | -      | -      | -      | -      | -      |
| Other liability             | -      | -      | -      | -      | -      |
| Non current liabilities     | -      | -      | -      | -      | -      |
| Total Liabilities           | 1.49   | 1.10   | 1.09   | 8.66   | 11.23  |
| Net Assets                  | 6.77   | 27.73  | 29.17  | 39.09  | 55.31  |
|                             |        |        |        |        |        |
| Contributed Equity          | 41.53  | 67.82  | 67.82  | 67.82  | 67.82  |
| Retained earnings           | -39.10 | -44.43 | -42.98 | -33.06 | -17.35 |
| Reserves/Other              | 4.33   | 4.33   | 4.33   | 4.33   | 4.83   |
| Total equity                | 6.77   | 27.73  | 29.17  | 39.09  | 55.31  |

| Statement of Cashhows             |       |       |       |       |       |
|-----------------------------------|-------|-------|-------|-------|-------|
| A\$'000s                          | FY24a | FY25e | FY26e | FY27e | FY28e |
| Net profit for period             | -5.41 | -5.33 | 1.44  | 9.92  | 15.71 |
| Depreciation & Amortisation       | 0.60  | 0.59  | 0.58  | 0.40  | 0.40  |
| Changes in working capital        | 1.15  | 0.93  | 1.00  | -0.60 | 0.60  |
| Other                             | -0.27 | -     | -     | -     | -     |
| Operating cash flow               | -3.92 | -3.82 | 3.02  | 9.72  | 16.71 |
|                                   |       |       |       |       |       |
| Payments for PPE                  | -     | -     | -     | -     | -     |
| Other payments                    | -     | -     | -     | -     | -     |
| Proceeds from asset sale          | -     | -     | -     | -     | -     |
| Investing cash flow               | -     | -     | -     | -     | -     |
| Equity raised                     | _     | 24.11 | _     | _     |       |
| Transaction costs                 | -     | -1.66 |       |       | -     |
| Proceeds from exercise of options | 2.76  | -1.00 | -     | -     | -     |
| Borrowings                        | 2.70  | -     | -     | -     | -     |
| 0                                 | -     | -     | -     | -     | -     |
| Other                             | -     | -     | -     | -     | -     |
| Financing cash flow               | 2.76  | 22.44 | -     | -     | -     |
| Free cash flow                    | -3.92 | -3.82 | 3.02  | 9.72  | 16.71 |
| Net cash flow                     | -1.16 | 18.63 | 3.02  | 9.72  | 16.71 |
| Effects of exchange rate          | 0.00  | -     | -     | -     | -     |
| Cash year end                     | 2.12  | 20.75 | 23.76 | 33.48 | 50.20 |
| Investment Fundamentals           |       |       |       |       |       |
| investment rundamentais           | FY24a | FY25e | FY26e | FY27e | FY28e |
| Liquidity                         |       |       |       |       |       |
| Quick Ratio                       | 0.2   | 0.8   | 1.7   | 1.0   | 1.1   |
| Solvency                          |       |       |       |       |       |
| Debt to Equity                    | 0.0   | 0.0   | 0.0   | 0.0   | 0.0   |
| Debt to Assets                    | 0.0   | 0.0   | 0.0   | 0.0   | 0.0   |
| LT Debt to Assets                 | 0.0   | 0.0   | 0.0   | 0.0   | 0.0   |
| Profitability                     |       |       |       |       |       |
| Net Margin                        | n/a   | n/a   | 23%   | 22%   | 24%   |
| ROA                               | -58%  | -29%  | 5%    | 25%   | 27%   |
| ROE                               | -76%  | -31%  | 5%    | 29%   | 33%   |
| Valuation (at Target Price)       | . 0,5 | 01/0  | 2,0   | 2070  | 23/0  |
| P/E                               | n/a   | 134.1 | 19.5  | 12.3  | 7.7   |
| EV/EBITDA                         | n/a   | n/a   | 64.4  | 11.0  | 6.3   |
| Р/В                               | 4.7   | 2.9   | 2.9   | 2.9   | 2.9   |

# **Key Risks**

# **Regulatory and Clinical Development Risks**

Echo IQ's commercial success heavily depends on obtaining and maintaining regulatory approvals, such as FDA 510(k) clearances and reimbursement codes from entities like the Centers for Medicare & Medicaid Services (CMS). EchoSolv-AS has secured FDA clearance; however, Echo IQ's recent unsuccessful application to the AMA CPT Editorial Panel for a dedicated Category III CPT code significantly increases uncertainty around future reimbursement and could impact broader adoption. EchoSolv-HF remains subject to regulatory approval, adding further uncertainty regarding timelines and outcomes. Any delays or adverse decisions could materially affect market entry timelines and potential revenue streams.

# **Reimbursement Risk**

EchoSolv's adoption relies substantially on adequate reimbursement from healthcare payors, including Medicare and commercial insurers. Currently, EchoSolv-AS is billed under Miscellaneous CPT code 93799, providing reimbursement typically between US\$100 to US\$150 per use, but only 20-40% of claims are successfully reimbursed. The recent rejection of Echo IQ's application for a dedicated Category III CPT code means that reimbursement remains sporadic and uncertain, increasing financial risk and potentially deterring hospitals from subscription commitments. Without securing a dedicated CPT code or alternative reimbursement such as NTAP or APC, the potential for market penetration and revenue growth is significantly constrained.

## Market Adoption and Competition Risk

Echo IQ competes in a rapidly evolving and highly competitive medical technology market. Competitors offering AI-enhanced diagnostic solutions such as HeartFlow's FFRCT and IDx-DR have experienced significant market adoption following successful CPT code approvals and clear reimbursement pathways. Echo IQ's inability to secure a dedicated CPT code places it at a competitive disadvantage, potentially slowing market uptake. Additionally, hospitals' and physicians' unpredictable adoption rates of new technologies, exacerbated by reimbursement uncertainties, could further impede EchoSolv-AS's market penetration and scale-up efforts.

# Intellectual Property (IP) Risk

Echo IQ's long-term value depends substantially on protecting its intellectual property, including proprietary algorithms and datasets such as the National Echo Database Australia (NEDA). While multiple patents have been filed, there is no guarantee these will be granted or effectively enforceable. Risks also include potential third-party litigation or infringement claims, impacting commercialisation capabilities and risking replication by competitors.

## **Data Security and Privacy Risk**

Echo IQ's products rely on extensive analysis of patient data, making cybersecurity and data privacy critical concerns. Breaches or cybersecurity failures could significantly damage the company's reputation, lead to legal liabilities, and impose substantial financial penalties. Additionally, stringent international regulations regarding data protection introduce compliance complexity, increasing operational costs and resource allocation.

# Access to Capital and Funding Risk

Echo IQ currently maintains adequate cash reserves; however, ongoing development, commercialisation, and market expansion plans may require additional capital. The recent rejection by the AMA may negatively influence investor sentiment and impact the company's ability to secure future funding on favourable terms or at all. Failure to obtain necessary funding could significantly delay or halt growth strategies and product deployment.

## **Personnel Risk**

Echo IQ's operational effectiveness hinges on retaining executive management and specialised technical personnel, particularly following recent strategic US appointments. Loss of key personnel or difficulty in attracting and retaining skilled professionals within the competitive AI and healthcare markets could negatively affect the company's ability to successfully execute its commercialisation plans.

## **Technological Development and Product Performance Risk**

EchoSolv-AS and EchoSolv-HF have demonstrated robust results in controlled clinical trials and validation studies; however, real-world outcomes may differ significantly. Unforeseen technical issues, reduced accuracy in diverse clinical settings, or integration difficulties into hospital workflows could negatively impact market acceptance, slowing revenue growth and adoption rates.

## **Economic and Market Conditions Risk**

General macroeconomic factors, including economic downturns, market volatility, and shifting healthcare policies, particularly in key markets like the US, can affect healthcare providers' capital expenditure decisions and patient volumes. These economic uncertainties, combined with existing reimbursement challenges, could further slow the adoption of new technologies such as EchoSolv-AS, impacting Echo IQ's market penetration and revenue forecasts.

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